Scancell Holdings Plc

Interim Results for the six months ended 31 October 2013

Positive immune response data and further funding supports future development

Scancell Holdings plc, ('Scancell' or the 'Company') the developer of novel immunotherapies for the treatment of cancer, announces results for the six months ended 31 October 2013.

Highlights during the period:

- Recruitment of 8mg dose patient cohort continues as part of the previously announced extension to Part 1 of the Phase1/2 study of ImmunoBody® vaccine, SCIB1 in patients with advanced melanoma
    - Data anticipated by 2014 calendar year end
- Planning for preclinical and clinical development of Modi-1, lead pipeline vaccine from Moditope® platform underway
    - Provisionally positioned as a novel immunotherapeutic for the treatment of triple-negative breast cancer, ovarian and endometrial cancers
    - First in-man clinical studies are scheduled to start in 2016
- Australia becomes first jurisdiction to grant DNA ImmunoBody® technology patent. Counterpart pending in major territories around the globe
- Operating loss for the period, £1.31m (2012: loss of £0.99m). Net loss £ 1.19m (2012: loss £0.92m)
- Cash at bank at 31 October 2013 was £6.40m (30 April 2013: £1.49m), following a Placing and Open Offer of shares in August that raised £6.09 million (net of expenses)

Post period highlights:

- Important positive data from Part 2 as well as an update from Part 1 of the on-going Phase 1/2 clinical trial with SCIB1 in patients with Stage III/IV melanoma were announced today (see separate announcement)
    - Melanoma-specific immune response seen in all Part 2 patients
    - Continuing positive survival trend in Part 1 subjects, although patient numbers are small
    - No serious adverse events reported
- Scancell granted an extension of the Option to commercialise Ichor's proprietary Trigrid™ electroporation delivery system with SCIB1

Richard Goodfellow, Joint CEO of Scancell, said:
"We are delighted with the results and progress generated from both our ImmunoBody® and Moditope® platform technologies during the period. In particular, the immune response data released today from our lead programme, the SCIB1 ImmunoBody® vaccine for advanced melanoma, has exceeded our highest expectations. We anticipate reporting data from the high dose 8mg arm of this Phase 1/2 trial by 2014 calendar year end. While treated patient numbers are small, we believe our results to date add to the growing body of evidence that suggests that training T cells to target and control tumour growth could be one of the most promising new ways of treating cancer. With that in mind, the discovery of the Moditope® platform technology could add a new dimension to cancer immunotherapy and form the basis of a completely new class of immuno-oncology treatments. We are actively planning the preclinical and clinical

development for Modi-1, our lead vaccine arising from this platform, as an immunotherapeutic provisionally for the treatment of triple-negative breast cancer, ovarian and endometrial cancers.

"As previously indicated at the time of our investor update in October, in view of the short to medium term licensing and partnership potential that both the Moditope® and ImmunoBody® programmes now bring to the Company, our strategy requires a more flexible approach. Whilst we are still fully focused on securing a sale of the business at the earliest opportunity, we will also consider technology validating and revenue generating deals on each platform in order to enhance the value of the Company when it is eventually sold."

For Further Information:

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About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms. Scancell's first ImmunoBody®, SCIB1 is being developed for the treatment of melanoma and is in Phase 1/2 clinical trials. Preliminary evidence from Part 1 of the study showing that SCIB1 produced an immune response which might be associated with clinical benefit in patients with malignant melanoma was released in December 2012.

Scancell's ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system; the helper cell system where inflammation is stimulated at the tumour site; and the cytotoxic T-lymphocyte or CTL response where immune system cells are primed to recognise and kill specific cells.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4 that destroy tumours without toxicity. The Directors believe that the Moditope® platform could play a major role in the development of safe and effective cancer immunotherapies in the future.

CHAIRMAN'S STATEMENT

I am pleased to report the Company's interim results for the six month period ended 31st October, 2013. During this period the Group has continued progress with the SCIB1 clinical trials and in August 2013 raised £6.1m (net proceeds) in additional investment through a placing and open offer of shares. These funds will enable the Company to commence work on the pre-clinical development of the first Moditope® immunotherapy product and will provide working capital for the completion of the existing SCIB1 clinical trials as well as enable the Company to recruit the further ten patients for the 8mg cohort of the Phase 1/2 trial.

We have also announced today (see separate release) the extremely encouraging new results from the ongoing Phase 1/2 clinical trial in patients with advanced melanoma. This data from Part 2 of the trial shows that all 14 patients produced a melanoma-specific immune response to treatment and all are still alive. Only three patients have any evidence of disease progression to date. In addition, the four patients from Part 1 of the study who were still alive at the time of the Part 1 report (December 2012) are still alive with a median survival time since treatment commenced of 25 months. Furthermore no serious drug related adverse events have been reported.

Financial

Profit and Loss Account
The Group made an overall operating loss for the six month period to 31st October 2013 of £1,306,556 (2012: loss of £989,981).

Overall the loss for the six month period was £1,187,574 (2012: loss £923,020).

Balance Sheet
The cash at bank at 31 October 2013 was £6,395,927 (30 April 2013: £1,491,320) and net assets amounted to £10,006,318 (30th April, 2013: £5,092,145)

SCIB1 melanoma vaccine

Clinical Trial

Additional encouraging results from the on-going Phase 1/2 clinical trial with SCIB1 in patients with Stage III/IV melanoma were announced today (see separate announcement).

In Part 1 of the study, 5/6 patients allocated to the 2mg and 4mg dose cohorts and who received at least three doses of SCIB1 produced a melanoma-specific immune response to treatment and 4/6 are still alive. In one of these patients all of the lung metastases showed partial or complete regression during treatment. All four surviving patients from Part 1 are still alive after a further 12 months on study. The median survival time from study entry in these two higher dose groups is now 25 months, although in three of these patients there is evidence of disease progression.

Part 2 of the study was conducted in 14 patients with resected Stage III/IV disease. All 14 patients (100%) produced a melanoma-specific SCIB1-induced T cell response to treatment. Only three patients have experienced progressive disease to date and all patients are still alive. The median survival time since initiating treatment with SCIB1 in Part 2 is currently 15 months and 21 months from diagnosis of metastatic disease. Six of these patients are continuing on extended, long-term treatment with SCIB1.

There have been no serious drug-related adverse events to date.

These encouraging results confirm that Scancell's SCIB1 ImmunoBody® therapy is producing a melanoma-specific immune response in patients with Stage III/IV melanoma; this is particularly evident in Part 2 patients with resected disease. Together with the immunological and clinical data from Part 1 of the study, the results suggest that the immune responses induced might also be contributing to the control of tumour in these patients.

As a result of the positive results and minimal side effects seen with the 4mg dose, Scancell commenced evaluating an 8mg dose in parallel with Part 2 of the Phase 1/2 study. The higher 8mg dose SCIB1 study has been implemented for two reasons:

Firstly, one of the goals of Part 1 of the Phase 1/2 study was to establish a "maximally tolerated dose" of SCIB1 for use in Part 2. As there were no drug related side effects observed at 4mg, a maximally tolerated dose was not reached and a higher dose could improve the immune response even further.

Secondly, we were pleased to see a significant effect on tumour burden in one late stage patient in the Part 1 study. The Part 2 study, however, is primarily designed to assess immune response in resected Stage III/IV patients and although we will be monitoring the time to disease progression, we will not be able to measure an effect on tumour size. The extended Part 1 study using the 8mg dose is in patients with tumour load and will therefore provide the opportunity to assess whether we can reproduce the valuable data reported from Part 1 in an additional group of patients and at a higher dose. Data from this cohort of patients is expected in by 2014 calendar year end.

Moditope® vaccine technology platform

The Company has developed a new platform technology, Moditope® which has been used to develop the lead product, which will henceforth be described as Modi-1. Planning is underway for the preclinical and clinical development of Modi-1 as an immunotherapeutic, provisionally for the treatment of triple-negative breast cancer, ovarian and endometrial cancers. First in-man clinical studies are scheduled to start in 2016. Moditope® harnesses CD4+ cells to eradicate tumours and represents a new class of immunotherapeutic agents. The platform deploys citrullinated tumour-associated peptide epitopes to overcome self-tolerance and destroy tumour cells, with no requirement for blockade inhibitors (for example CTLA4 antibodies and PD-1 inhibitors). It can potentially be expanded to develop multiple immunotherapeutic agents for different cancers.

The ImmunoBody® platform induces a high avidity CD8+ T cell response to tumour associated antigens. As the Moditope® platform stimulates a potent CD4+ T cell response to modified self-antigens both platforms are complementary relying on a response by different classes of T cell for their therapeutic effect. Thus, in principle, a combination of ImmunoBody® and Moditope® derived therapeutics may be a powerful approach to the treatment of both early and late stage cancers.

Patents

A patent for Scancell's DNA ImmunoBody® technology has been granted in Australia. This is the first jurisdiction to approve the DNA patent and is a key landmark on the road to comprehensively protecting Scancell's DNA ImmunoBody® platform technology.

The patent, which covers the DNA ImmunoBody® platform technology and is of importance for the protection of Scancell's entire pipeline of ImmunoBody® vaccines, has also been filed in the US, Europe and other major markets. The composition of matter patent for SCIB1, Scancell's ImmunoBody® vaccine for the treatment of melanoma, has already been granted in Europe, Turkey and South Africa. Scancell's protein ImmunoBody® patent has also been approved in the US, Europe, Japan and Australia.

A broad patent for Scancell's Moditope® has been filed to protect this platform and covers the use of multiple tumour-associated modified epitopes for the treatment of cancer.

Ichor

Scancell signed an agreement with Ichor in July 2009 which provides for the supply and use of the TriGrid™ device for Scancell's pre-clinical and clinical studies with SCIB1 and gives Scancell an option ('The Option') to license TriGrid™ for commercial use on payment of certain undisclosed milestones and royalties. The Option could be exercised at any time up to July 2014. In return, Ichor was granted share options to subscribe for Scancell shares at a subscription price of 4.5p including an option over 1,592,310 shares upon regulatory approval to start clinical trials being granted in the UK.

Since the end of the period, Scancell has been granted an extension of The Option to commercialise Ichor's proprietary TriGrid™ electroporation delivery system with SCIB1, Scancell's ImmunoBody® vaccine for the treatment of melanoma. Under the terms of the extension, Scancell's Option, which had been due to expire in July 2014, will be extended until July 2016. In exchange, Scancell agreed to waive the two year lock-in period following the exercise of Ichor's options over 1,592,310 shares at 4.5p which have been subsequently placed on the market.

Share Capital – Placing and Open Offer

On 1st August 2013 the shareholders of the Company approved resolutions for; (i) the placing of 20,000,000 ordinary 0.1p shares at a price of 22.5p and (ii) an open offer to qualifying shareholders, who had not taken part in the placing, to subscribe for 8,888,888 ordinary 0.1p shares at a price of 22.5p. Following the approval of these resolutions the company raised £6.1m, net of costs.

Outlook

The results released today from Part 2 of the Phase 1/2 study with the SCIB1 vaccine in advanced melanoma support the encouraging results from Part 1 of the study reported last year. Importantly, we have confirmed that SCIB1 induces a consistent melanoma-specific immune response in Stage III/IV melanoma patients, especially in those with resected disease. Whilst the numbers are still small, the results suggest that SCIB1 may be contributing to prolonged survival by controlling tumour growth. We remain confident that, as further long-term data is generated, both in these patients and those treated with the higher 8mg dose, the clinical and commercial potential of Scancell's ImmunoBody® vaccine approach will be fully apparent. The results from this trial to date have exceeded our highest expectations and support our belief that the highly targeted ImmunoBody® approach is delivering potent T cells that can control malignant disease and adds to the growing body of evidence that suggests that training T cells to target and control tumour growth could be of the most promising new ways of treating cancer. Furthermore, in patients with more extensive metastases, it is feasible that combining SCIB1 with the latest checkpoint inhibitor drugs, which allow T cells to work better within the tumour environment, may offer further patient benefit.

The discovery of the Moditope® platform technology and its ability to induce potent CD4+ T cells against tumour associated epitopes could add a new dimension to cancer immunotherapy and form the basis of a completely new class of immune-oncology treatments.

As previously indicated at the time of our investor update in October, in view of the short to medium term licensing and partnership potential that both the Moditope® and ImmunoBody® programmes now bring to the Company, our strategy requires a more flexible approach. Whilst we are still fully focused on securing a sale of the business at the earliest opportunity, we will also consider technology validating and revenue generating deals on each platform in order to enhance the value of the Company when it is sold.

David Evans
Chairman

Scancell Holdings plc
Consolidated Income Statement
for the six months to 31st October 2013

	Unaudited six months 31/10/2013 £	Unaudited six months 31/10/2012 £	Audited Year to 30/04/2013 £
Continuing operations			
Development expenses	(666,766)	(564,709)	(1,452,317)
Administrative expenses	(639,790)	(425,273)	(731,672)
OPERATING LOSS	(1,306,556)	(989,982)	(2,183,989)
Interest receivable and similar income	3,982	17,904	30,037
LOSS BEFORE TAXATION	(1,302,574)	(972,078)	(2,153,952)
Tax on loss on ordinary activities	115,000	49,058	252,008
LOSS FOR THE PERIOD	**(1,187,574)**	**(923,020)**	**(1,901,944)**
EARNINGS PER ORDINARY SHARE (PENCE) Note 2			
Basic	(0.57)	(0.47)	(0.98)
Diluted	(0.57)	(0.47)	(0.98)

Consolidated Statement of Comprehensive Income for the period ended 31st October 2013

Profit/(Loss) for the period	(1,187,574)	(923,020)	(1,901,944)

Scancell Holdings plc
Consolidated Statement of Changes in Equity
for the six month period to 31st October 2013

	Share capital £	Share premium account £	Share option reserve £	Retained earnings £	Total Equity £
At 1st May 2013	194,470	9,904,733	509,914	(5,516,972)	5,092,145
(Loss) for the period				(1,187,574)	(1,187,574)
Share issue (net of expenses)	28,888	6,061,481			6,090,369
Share option costs			11,378		11,378
At 31st October 2013	223,358	15,966,214	521,292	(6,704,546)	10,006,318
At 1st May 2012	194,470	9,904,733	487,162	(3,615,028)	6,971,337
(Loss) for the period				(923,020)	(923,020)
Share option costs			12,200		12,200
At 31st October 2012	194,470	9,904,733	499,362	(4,538,048)	6,060,517
At 1st May 2012	194,470	9,904,733	487,162	(3,615,028)	6,971,337
(Loss) for the period				(1,901,944)	(1,901,944)
Share option costs			22,752		22,752
At 30th April 2013	194,470	9,904,733	509,914	(5,516,972)	5,092,145

Scancell Holdings plc
Consolidated Statement of Financial Position
as at 31st October 2013

	Unaudited	Unaudited	Audited
	31/10/2013	31/10/2012	30/04/2013
	£	£	£
ASSETS			
Non-current assets			
Plant and equipment	134,937	140,092	131,655
Goodwill	3,415,120	3,415,120	3,415,120
	3,550,057	3,555,212	3,546,775
Current assets			
Trade and other receivables	123,827	152,152	117,164
Income tax assets	367,000	49,058	252,000
Cash and cash equivalents	6,395,927	2,568,359	1,491,320
	6,886,754	2,769,569	1,860,484
TOTAL ASSETS	10,436,811	6,324,781	5,407,259
LIABILITIES			
Current liabilities			
Trade and other payables	430,493	264,264	315,114
NET CURRENT ASSETS	6,456,261	2,505,305	1,545,370
NET ASSETS	10,006,318	6,060,517	5,092,145
TOTAL EQUITY			
Called up share capital	223,358	194,470	194,470
Share premium account	15,966,214	9,904,733	9,904,733
Share option reserve	521,292	499,362	509,914
Retained earnings	(6,704,546)	(4,538,048)	(5,516,972)
	10,006,318	6,060,517	5,092,145

Scancell Holdings plc
Consolidated Cash Flow Statement
for the six month period to
31st October 2013

	Unaudited six months 31/10/2013 £	Unaudited six months 31/10/2012 £	Audited Year to 30/04/2013 £
Cash flows from operating activities			
Operating (loss) for the period	(1,306,556)	(989,981)	(2,183,989)
Depreciation	16,457	16,559	44,006
Share based payment expense	11,378	12,200	22,752
Operating (loss) profit for the year before changes in working capital	(1,278,721)	(961,222)	(2,117,231)
(Increase)/decrease in trade and other receivables	(6,663)	(21,046)	13,943
(Decrease)/increase in trade and other payables	115,378	(20,119)	30,731
Cash generated from operations	(1,170,006)	(1,002,387)	(2,072,557)
Income taxes received	-	74,220	74,226
Net cash from operating activities	(1,170,006)	(928,167)	(1,998,331)
Cash flows from investing activities			
Asset acquisition	(19,738)	(50,385)	(69,393)
Finance income	3,982	17,904	30,037
Net cash used by investing activities	(15,756)	(32,481)	(39,356)
Cash flows from financing activities			
Proceeds from issue of share capital	6,500,000	-	-
Expenses of share issue	(409,631)	-	-
Net cash generated from financing activities	6,090,369	-	-
Net increase/(decrease) in cash and cash equivalents	4,904,607	(960,648)	(2,037,687)
Cash and cash equivalents at beginning of the year	1,491,320	3,529,007	3,529,007
Cash and cash equivalents at end of the period	6,395,927	2,568,359	1,491,320

Scancell Holdings plc
Notes to the Interim Financial Statements
for the period to 31st October 2013

1 Basis of preparation

This interim statement for the six month period to 31st October 2013 is unaudited and was approved by the Directors on 6th December, 2013. The financial information contained in the interim report has been prepared in accordance with the accounting policies set out in the annual report and accounts for the year ended 30th April 2013.

The financial information contained in the interim report does not constitute statutory accounts as defined in section 434 of the Companies Act 2006. The financial information for the full preceding year is based on the statutory accounts for the year ended 30th April 2013, upon which the auditors, Champion Accountants LLP, issued an unqualified audit opinion which did not contain any statement under section 498(2) or 498(3) of the Companies Act 2006. The audited statutory accounts for the year ended 30 April 2013 have been lodged with the Registrar of Companies.

As permitted, this interim report has been prepared in accordance with AIM Rule 18 and not in accordance with IAS 34 "Interim Financial Reporting" therefore it is not fully in compliance with IFRS as adopted by the European Union.

2 Earnings per share

Basic earnings per share, from continuing operations, is calculated by dividing the earnings attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year.

The calculations of earnings per share are based on the following losses and numbers of shares.

	6 months to 31/10/2013	6 months to 31/10/2012	Year ended 30/04/2013
Loss after taxation	(1,187,574)	(923,020)	(1,901,944)
Weighted average number of shares	208,677,135	194,469,485	194,469,485
Basic earnings per share	(0.57)p	(0.47)p	(0.98)p

At 31st October 2013 the Company had 223,358,373 Ordinary Shares of 0.1p in issue.

3 Taxation

Taxation for the six months ended 31st October 2013 is based on the effective rates of taxation which are estimated to apply for the year ended 30th April 2014.

4 Interim results

These results were approved by the Board of Directors on 6th December, 2013. Copies of the interim report are available to the public from the Group's registered office and the Group's website, www.scancell.co.uk.